UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL NO. 1456**
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL ACTIONS	**Judge Patti B. Saris**

CONSOLIDATED REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE MASTER CONSOLIDATED CLASS ACTION COMPLAINT

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RULES AND REGULATIONS

Plaintiffs' opposition is notable more for what it concedes than for what it contests. Plaintiffs essentially concede the legislative and regulatory history showing that Congress and HHS knew of the significant gap between many published AWPs and provider acquisition cost (for some drugs, the gap was 1000%). Nor do plaintiffs challenge the legislative history showing that Congress, knowing about the large spreads, continued to base reimbursement on published AWPs to ensure adequate physician reimbursement and outpatient access. Backing away from "actual acquisition costs," plaintiffs now ask the Court to impose a new definition of AWP -- a "real average of real prices." This new definition, which is merely a variant of actual provider acquisition cost, was *specifically* rejected by Congress in 2000, when it barred HHS from using such average prices. Plaintiffs' request that the Court reverse this legislative judgment and enact a new "real prices" reimbursement system takes this Court well beyond its Article III jurisdiction.

Nor can the Court credit plaintiffs' reliance on the TAP proceedings. In pleading guilty to a criminal Prescription Drug Marketing Act violation, TAP made no admissions regarding AWP. In its contemporaneous civil settlement, TAP made no admissions at all. Of course, settlements by companies not before the Court -- whether civil or criminal -- should play no role in determining whether these plaintiffs have carried their pleading burden under Rules 12(b)(6) and 9(b). Remarkably, plaintiffs make no bones about their "where there's smoke, there's fire" approach -- they freely acknowledge hauling dozens of companies into this MDL with no particulars because everyone supposedly is "juridically linked" by alleged "common practices" (Pl. Opp. at 50), a position that finds no support in the law, as the individual reply briefs demonstrate. Likewise, the Class 2 allegations, in which plaintiffs seek to place at issue *thousands* of non-Medicare drugs, are defective because they are based on nothing more than the

notion that if companies marketed the spread to doctors for Medicare drugs, they must have marketed it to PBMs for non-Medicare drugs that were reimbursed by private insurers not covered by the Medicare AWP statute.

Equally unacceptable is the plaintiffs' effort to use recent press statements and ongoing investigations involving a few companies as evidence of what Congress and HHS knew about AWP. The evidence of Congressional and agency knowledge about AWP must be derived from traditional regulatory and legislative materials, not from the post-hoc statements of a single Congressman or reports of investigations.

ARGUMENT

I. THE COURT MAY PROPERLY CONSIDER THE CONGRESSIONAL AND ADMINISTRATIVE MATERIALS REGARDING "AWP."

Plaintiffs first question whether the Court may consider the regulatory and legislative history materials attached to our opening brief. Such consideration is not only appropriate but required. First, these materials are necessary to interpret the AWP statute and regulation, Congress' intent, and HHS' administration of the AWP system within the Medicare program. It is a routine judicial function, in deciding a motion to dismiss, to consider public government reports and legislative materials in interpreting statutes and regulations and divining legislative intent.[1] Second, the Court may consider such materials where, as here, plaintiffs

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[1] *See Cipollone v. Ligget Group, Inc.*, 505 U.S. 504, 519 & n.16 (1992) (in interpreting statute, Court looks at statute's "regulatory context"; criticizing dissent for reading statute without looking at the "regulatory setting in which Congress acted"); *Anheuser-Busch, Inc. v. Schmoke*, 63 F.3d 1305, 1312 (4th Cir. 1995) (appropriate to consider legislative history on motion to dismiss), *vacated on other grounds*, 517 U.S. 1206 (1996); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1197 (3d Cir. 1993) (courts may consider "published reports of administrative bodies," in deciding motions to dismiss); *Wai v. Allstate Ins. Co.*, 75 F. Supp.2d 1, 11 (D.D.C. 1999) (considering statute's "legislative history and agency interpretations" on motion to dismiss).

claims raise subject matter jurisdiction issues under Rule 12(b)(1). *See Dynamic Image Techs., Inc. v. United States,* 221 F.3d 34, 38 (1st Cir. 2000). Third, plaintiffs' suggestion that the Court should disregard the regulatory and legislative context and simply apply dictionary definitions to a term of art like "average wholesale price" is contrary to settled principles of statutory construction.[2]

In any event, the plaintiffs never take issue with the basic findings of the cited government and legislative reports. They assert only that the particular report either is "not relevant to the case," without explaining why, or acknowledge that defendants' "observation is generally accurate," or concede that "Plaintiffs do not dispute" or "contest" the contents of a particular report. *See* Exhibit 1 to Sobol Aff.

II. THE COURT CANNOT HOLD THAT DEFENDANTS SHOULD HAVE REPORTED THE "REAL AVERAGE OF REAL PRICES."

In the opening brief, defendants demonstrated that the Court cannot hold that AWP approximates actual acquisition cost because Congress directed Medicare to rely on published AWPs, knowing and expecting that those prices were often well above provider acquisition cost. Congress made this policy decision to base reimbursement on what HHS described as "non-discounted sticker prices" because it wanted to preserve adequate reimbursement for the administering physician. Other than very minor quibbles with a few of these government reports, the plaintiffs do not and cannot dispute this AWP regulatory and legislative history. Plaintiffs never dispute, for example, the reports showing that AWPs were

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[2] *See Corning Glass Works v. Brennan*, 417 U.S. 188, 201 (1974) ("[W]here Congress has used technical words or terms of art, 'it (is) proper to explain them by reference to the art or science to which they (are) appropriate.'"); *Commonwealth of Massachusetts v. Blackstone Valley Elec. Co.,* 67 F.3d 981, 986-88 (1st Cir. 1995) (plain meaning approach to terms of art is misplaced); Ex. 31 ("within the pharmaceutical industry, AWP means non-discounted list price") (HHS-IG Report).

"not designed to reflect physicians' costs," and that many AWPs were as much as "1000 percent per dosage more than acquisition costs," Ex. 2; *see also* Ex. 29, App. II & III (for other drugs, the provider acquisition costs were 83% lower than the published AWPs).

Instead, the plaintiffs assert that HHS and Congress never intended to condone fraud and "misleading, inflated" AWPs. This is true, of course, but it begs the question of what Congress meant AWPs to mean, for only by reference to congressional intent can any reported AWP be judged to be false or misleading. Plaintiffs bear the burden, as in any fraud case, to detail how the prices allegedly reported by the defendants were fraudulent *and* what prices should have been reported.[3]

Plaintiffs have offered two definitions of AWP, but both definitions are directly contrary to Congress' understanding of the term. Contrary to plaintiffs' present denials, the Master Complaint repeatedly alleged that the companies should have reported actual provider acquisition cost.[4] Running away from this core allegation and denying it ever existed, plaintiffs now contend that AWPs should be "a real average of real prices" (Pl. Opp. at 14). As demonstrated in defendants' opening brief, the Court cannot interpret the AWP regulation to find

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[3] *See, e.g., Williams v. WMX Tech.*, 112 F.3d 175, 177 (5th Cir. 1997) ("articulating the elements of fraud with particularity requires a *plaintiff* to specify the statements contended to be fraudulent . . . *and explain why the statements were fraudulent*") (emphasis added). In this regard, the plaintiffs are simply wrong that "alleging that defendants reported fictitious AWPs suffices" (Pl. Opp. at 11.) *See Ruskin v. TIG Holdings*, 1999 WL 756466, at *4 (S.D.N.Y. Sept. 24, 1999) (complaint dismissed under Rule 9(b) because it did not "explain why the statements were fraudulent").

[4] *See* Master Cplt. ¶¶ 4, 5 (AWPs that are higher than the actual costs paid by providers or PBMs are "inflated"); *id.*¶ 136 (defendants should have reported "actual transaction price data -- the amounts charged to providers or others for their drugs"); *id.* ¶ 164 (the prices reported should have reflected the "actual pricing structure" or the drug's "real cost"); *id.* ¶ 169 (defendants' committed "AWP Fraud" because they knew that there were significant discrepancies between the reported AWP for drugs and "the prices actually paid by providers and PBMs for those same drugs"); *id.* ¶¶ 388, 415, 442 (AWPs were inflated because they did "not reflect the true price paid" for the drug by the purchaser).

that the companies should have reported prices approximating anything close to provider acquisition cost. And plaintiffs' new proposed definition -- "a real average of real prices" -- is precisely the approach that Congress *rejected* when it enacted BIPA in response to the Administration's proposal to use its own survey of actual prices. *See* Opening Mem. at 13.[5] Plaintiffs also rely heavily on the views of Congressman Stark, but the numerous bills he has advocated to require Medicare payments to be based on actual market prices have never been enacted. *See, e.g.*, Exs. 6-9, 13, 17, 19.

In our constitutional system, the Court cannot adopt plaintiffs' AWP definition, enact Congressman Stark's bills, and do what Congress forbid HHS to do in 2000. Contrary to the plaintiffs' assertion (Pl. Opp. at 16), adoption of their AWP claims would require the Court to "rewrite the reimbursement rules" and establish a new Medicare reimbursement level for thousands of physicians and patients. If, as plaintiffs seek, reimbursement is based on a "real average of real prices" -- which for many drugs will be much lower than the published AWPs -- then that benchmark will reduce Medicare reimbursement to physicians by millions of dollars. Congress has declined to take this step because, *inter alia,* of concerns over access to care for the Medicare population and overall increases in Medicare expenditures if treatment shifts from outpatient settings to hospitals. It clearly is not a court's role to make the policy judgments plaintiffs advocate, especially in an area as complex as Medicare reimbursement, with far-reaching and unforeseeable consequences, and particularly when Congress and HHS are debating that very issue. As the decision in *Stephenson v. Shalala*, 87 F.3d 350 (9th Cir. 1996),

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[5] As recently as December 3, 2002, HHS stated that it would "continue, in accordance with its longstanding practice, to set a price for each drug based on 95% of AWP and [would] continue to rely on published compilations (*e.g.*, RedBook and First Data Bank) to identify wholesale drug prices." HHS/CMS, Transmittal No. AB-02-174, Attachment (Dec. 3, 2002) (Ex. 55, attached hereto).

demonstrates, the adequacy of physician reimbursement is a Medicare policy choice that must be resolved by the legislative and executive branches, not by a court.

It is in this narrow respect that the plaintiffs' claims are non-justiciable. Defendants have never argued, despite plaintiffs' protestations, that the Court lacks jurisdiction even to consider the AWP statute and regulations, or that the entire subject of Medicare reimbursement is a political question inappropriate for judicial resolution. Defendants' opening brief did not even cite *Baker v. Carr*, 369 U.S. 186 (1962), on which the plaintiffs base their rebuttal. Instead, defendants assert that the Court would exceed the limits of its jurisdiction if it recalibrated AWP and physician Medicare reimbursement in the manner sought by plaintiffs. The Ninth Circuit in *Stephenson* refused to interpret a Medicare term in the way plaintiffs sought because to do so would have required a reimbursement level that Congress and HHS had been unwilling to set. Just as in this case, Congress was "aware of the issue" in *Stephenson,* it had "participated in creating the present structure of reimbursement," and it was "considering its own changes to the system at this time." Under those circumstances, the court declined to intervene and "preempt Congressional action in this very delicate area of public policy." 87 F.3d at 355-56.[6]

Thus, the Court should either decline to define AWP in the manner suggested by plaintiffs (as the Ninth Circuit did in *Stephenson*) or rule as a matter of law that AWP cannot, given the undisputed AWP regulatory history, mean what plaintiffs now say it means. Either

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[6] The plaintiffs can take no comfort from the magistrate's unpublished report and recommendation on remand in *State of Minnesota v. Pharmacia Corp.*, C.A. No. 02-1779 (D. Minn. Sept. 27, 2000). In that case, the magistrate was never presented with the AWP regulatory history nor the justiciability issues presented by this case. Instead, the magistrate only addressed whether federal question jurisdiction existed as a result of the AWP allegations in that particular case.

way, the Court cannot hold that the companies should have reported the prices at which providers acquired the drugs or a "real average of real prices."

III. THE RICO CLAIMS SHOULD BE DISMISSED.

A. The RICO Claims Fail Because The Dozens of Putative Enterprises Are Deficient.

1. The Association In Fact Enterprises Fail The *Turkette* Standards.

Plaintiffs acknowledge, as they must, that an association in fact enterprise must (a) be an "ongoing organization" with (b) an existence "separate and apart" from the alleged fraud whose (c) members "function as a continuing unit" and (d) are "associated together for a common purpose of engaging in a course of conduct." *United States v. Turkette*, 452 U.S. 576, 583 (1981). Nor do plaintiffs contest the First Circuit's rule that "similarity of goals and methods does not suffice to show that an [association in fact] enterprise exists; what is necessary is evidence of systematic linkage, such as overlapping leadership, structural or financial ties, or continuing coordination." *Libertad v. Welch*, 53 F.3d 428, 443 (1st Cir. 1995) (interpreting *Turkette*). Instead, the plaintiffs contend that their putative association in fact enterprises -- the AWP, Publisher, and PBM enterprises -- satisfy these requirements because the Master Complaint parrots the *Turkette* requirements. Contrary to the plaintiffs' assertion that "[n]othing more is required" (Pl. Opp. at 21), the mere incantation of the *Turkette* standard is insufficient. *See Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 41 n.7 (1st Cir. 1991) (conclusory allegations insufficient to show existence of RICO enterprise).

With respect to the AWP Enterprises, plaintiffs concede that each enterprise includes a drug company and thousands of unnamed, "independent" physicians. As the plaintiffs acknowledge (Pl. Opp. at 21), the "Johnson & Johnson Group Provider Enterprise" includes every doctor in America who prescribed the J&J drugs Remicade and Procrit, used to treat

Crohn's disease and anemia, respectively. This would include, for example, a gastroenterologist in New Hampshire and a hematologist in Miami. All of these physicians are alleged to represent, together with J&J and "its officers and directors," an "ongoing organization" whose members "function as a continuing unit." Each of the other AWP Enterprises is similarly far-flung and most physicians are members of several. The PBM enterprises -- consisting of each defendant and scores of unnamed pharmacy benefit managers -- are also dispersed, diffused, and unconnected.

The plaintiffs never explain how these jumbled, sprawling, nationwide enterprises of physicians and PBMs could display an "ongoing organization" whose members "function as a continuing unit," particularly when the members of the enterprise do not even know one another. Plaintiffs never address the cases that have rejected such hub-and-spoke associations in fact. *See* Opening Br. at 28 n.24. Nor do the plaintiffs address the cases we cited rejecting associations in fact consisting of large numbers of individuals and entities. *See id.* at 28 n.22. Plaintiffs fail completely to allege or explain how these physician and PBM enterprises have a "systematic linkage, such as overlapping leadership, structural or financial ties, or continuing coordination." *Libertad*, 53 F.3d at 443.

The main case on which plaintiffs rely, *United States v. Patrick*, 248 F.3d 11 (1st Cir. 2001), supports the defendants, not the plaintiffs. In that case, the association in fact was the archetype RICO enterprise -- a small criminal street gang, not a sprawling nationwide collection of thousands of doctors or scores of PBMs. The court found only that a jury instruction reciting the *Turkette* factors was sufficient; it never held that no structure is required. In fact, the First Circuit has held that some form of "structural or financial ties" are required. *Libertad,* 53 F.3d at 443. More significantly, the court in *Patrick* found ample evidence from which the jury could

find structure and organization, *i.e.*, the gang members knew one another, the gang "was ongoing and identifiable," "it had colors and signs, it had older members who instructed younger ones, its members referred to the gang as family, and it had 'sessions' where important decisions were made, including decisions about taking action against rival drug dealers." *Patrick*, 248 F.3d at 19. By contrast, the AWP and PBM Enterprises are at the other end of the enterprise spectrum -- the members don't know one another, they have no identifying characteristics, and they are otherwise entirely unconnected.[7]

Even if thousands of unconnected physicians and scores of PBMs could form a group with "overlapping leadership" or "structural or financial ties" -- which they cannot -- these disparate groups still could not possess the requisite "common purpose of engaging in a course of conduct," as *Turkette* requires. Plaintiffs claim the requisite common purpose is established because the thousands of doctors and PBMs in these enterprises were linked with the companies by their shared desire to "make money" (Pl. Opp. at 24). This cannot be taken seriously. If plaintiffs' test applied, then all the participants in a common business venture, no matter how broad (*i.e.*, all online traders who want to make money), could be connected as a RICO enterprise. Recognizing this, the courts have rejected efforts to satisfy *Turkette* by alleging a

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[7] The enterprise of physicians and health care providers in *In re Managed Care Litigation*, 185 F. Supp.2d 1310 (S.D. Fla. 2002), on which plaintiffs rely, also differed significantly from the AWP and PBM Enterprises. In *In re Managed Care Litigation*, the enterprise was the defined Humana health network, which Humana "openly celebrates" and which had a specifically identifiable and promoted group of physicians and health care entities. *See* 185 F. Supp.2d at 1323-24. In a prior ruling, the same court found that "an entire nationwide or regional industry or profession" may not constitute a RICO enterprise. *In re Managed Care Litigation*, 135 F. Supp.2d 1253, 1262 (S.D. Fla. 2001). By contrast, the AWP and PBM Enterprises are just the kind of "random collection" of individuals "within a particular industry" that the court observed could not constitute a RICO enterprise. Unlike the Humana network, the doctors in each of the dozens of AWP Enterprises are never identified or promoted as a cohesive, ongoing unit.

common participation in a particular industry or through connection with a particular defendant. *See* Opening Br. at 29 n.25. In the case on which plaintiffs rely, *United States v. London*, 66 F.3d 1227 (1st Cir. 1995), the defendant was the owner and operator of the two enterprises at issue, a bar and a check-cashing service located in the bar. It was thus obvious that the defendant shared with his own businesses the quite narrow common purpose of running an unlawful money laundering operation. Once again, plaintiffs' reliance on a run-of-the-mill criminal case merely highlights the inadequacy of their sprawling AWP Enterprises.

The plaintiffs misunderstand defendants' argument with respect to the Publisher Enterprises, which consist of each defendant and the various publishers that report AWPs. Defendants never contended that an enterprise cannot consist of separate legal entities and so the cases cited by plaintiffs are completely irrelevant. An association in fact enterprise may consist of distinct legal entities but, like all associations in fact under RICO, the enterprise must *also* be an "ongoing organization" with an existence "separate and apart" from the alleged fraud, whose members "function as a continuing unit" and are "associated together for a common purpose of engaging in a course of conduct." *Turkette*, 452 U.S. at 583. In their opening brief, defendants demonstrated that each Publisher Enterprise did not exhibit any of these *Turkette* characteristics. The publisher enterprises are also hub-and-spoke enterprises -- each with the same spokes but different hubs. Defendants also showed that the common purpose allegedly linking the members of these putative associations -- the "selling, purchasing, and administering" of Medicare drugs -- was insufficient. As the First Circuit held in *Libertad*, "similarity of goals and methods does not suffice to show that an [association in fact] enterprise exists; what is necessary is evidence of systematic linkage, such as overlapping leadership, structural or financial ties, or continuing

coordination." *Libertad*, 53 F.3d at 443. The plaintiffs never allege any linkage among the various publishers other than their independent relationship with each defendant.

2. Plaintiffs Cannot Show That The Drug Companies "Operated Or Managed" The Private Third Party Payors.

Plaintiffs acknowledge, as they must, that to "conduct or participate" in the affairs of an enterprise, a defendant must participate in its "operation or management." *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993). To satisfy this test, it is not enough to allege that a defendant had a "business relationship" with the enterprise, or has victimized or defrauded the enterprise.[8]

Nevertheless, plaintiffs argue that the drug companies "operated or managed" the plaintiff third party payors by submitting inflated AWPs to a publisher, which were in turn relied upon by Medicare or a third party payor. The case on which plaintiffs rely, *Aetna Casualty Surety Co. v. P&B Autobody*, 43 F.3d 1546 (1st Cir. 1994), certainly does not support that proposition. Plaintiffs fail to acknowledge the key distinction in *Aetna* -- that the defendant worked with inside Aetna appraisers to execute the insurance fraud scam. *See Aetna*, 43 F.3d at 1560. This evidence of insider cooperation satisfied the *Reves* test, which is consistent with the Supreme Court's observation that one of the only ways for an "outsider," particularly a separate commercial entity, to satisfy the *Reves* test is through bribery or other internal infiltration. *See Reves*, 507 U.S. at 184. There is, of course, no such allegation in this case -- *i.e.*, that the plaintiff payors' own personnel somehow conspired with the drug companies to pay claims based upon AWP. At most, the plaintiffs allege that they are enterprises victimized by the

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[8] *See In re SmithKline Beecham Clinical Labs. Lab. Test Billing Practices Litig.*, 108 F. Supp.2d 84, 99 (D. Conn. 1999) ("[A]lthough [defendant's] billing practice may have *victimized* the [plaintiffs] that does not suffice to establish that [defendant] '*operated* or *managed*' the affairs of each of these alleged enterprises.") (emphasis in original).

alleged reporting of AWP, which is not enough under *Reves*. *See In re SmithKline Beecham Clinical Labs. Lab. Test Billing Practices Litig.*, 108 F. Supp.2d 84, 99 (D. Conn. 1999).

B. The RICO Claims Fail Because There Was No Direct Causation.

Plaintiffs concede (Pl. Opp. at 37) that recovery under civil RICO requires a *direct* connection between the alleged injury and the alleged misrepresentations. *See Willis v. Lipton*, 947 F.2d 998, 1000-02 (1st Cir. 1991). The plaintiffs claim they satisfy this requirement because the complaint alleges such a direct connection (Pl. Opp. at 37), but a conclusory allegation is not enough.[9] Nor is it sufficient merely to allege that it was "foreseeable" that plaintiffs might pay more for drugs. To the contrary, under civil RICO, alleging that "defendant's acts were a substantial cause of the injury, and that plaintiff's injury was reasonably foreseeable, are *additional elements*, not substitutes for alleging (and ultimately showing) a direct injury." *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 235-36 (2d Cir. 1999) (emphasis in original). It is equally insufficient simply to allege that the plaintiffs were a target or even the intended victim of the alleged scheme.[10]

Here, plaintiffs concede that the Medicare beneficiaries and health plans were *not* the principal target of the defendants' alleged misrepresentations. Under plaintiffs' theory, the

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[9] *See Birch Street Recovery Corp. v. Thomas*, 2000 WL 1513799, at *4 (D.N.H. July 29, 2000) (plaintiffs' "bald assertion that they were damaged as a direct and proximate result of the defendants' conduct" is insufficient under Rule 12); *Schmidt v. Fleet Bank*, 1998 WL 47827, at *8 (S.D.N.Y. Feb. 4, 1998) (RICO action dismissed where allegations are "entirely conclusory and simply parrot the statutory requirements.").

[10] *See Serv. Employees Int'l Union Health & Welfare Fund v. Philip Morris, Inc.*, 249 F.3d 1068, 1076 (D.C. Cir.) (allegation that plaintiff was an intended victim of defendants' scheme did not overcome the bar on remote RICO claims), *cert. denied sub nom. Republic of Guatemala v. Tobacco Inst., Inc.*, 122 S. Ct. 463 (2001); *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 242 (2d Cir. 1999) (allegation that defendants specifically intended to target plaintiff "does not overcome the requirement that there must be a direct injury to maintain this action").

primary goal of the defendants' alleged AWP reporting was to "induce providers [doctors] to prescribe their Covered Drugs." (Pl. Opp. at 37.) Even accepting plaintiffs' allegations, the higher prices that resulted for plaintiffs were a byproduct or secondary effect of each company's effort to increase market share vis-à-vis its competitors; defendants did not receive a penny of what plaintiffs paid to the providers. No matter how hard they try, plaintiffs cannot avoid the fact that the alleged misrepresentations were made to publishers (not plaintiffs), that doctors (not defendants) decided what to charge, and that either Congress and HHS (Class 1) or Third Party Payors (Class 2) established the particular reimbursement rates about which plaintiffs complain. Plaintiffs have no response to these facts, or to the many cases dismissing RICO claims where the alleged injuries were caused more directly by the intervening actions of others, including government agencies. *See* Opening Br. at 25 n.19.

Plaintiffs also concede (as they must) that they are indirect purchasers of the defendants' products. Plaintiffs never address the cases barring indirect purchasers from maintaining claims under RICO, except to say in a footnote that they were the "first victims" of the alleged scheme and were "out of pocket" "as a consequence." (Pl. Op. at 39, n.30.) But the courts have refused to carve out an exception to *Illinois Brick* where the indirect purchasers were the first or even predominant victims of the alleged fraud. *See Kansas v. Utilicorp United, Inc.*, 497 U.S. 199, 216 (1990); *McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 853, 855 (3d Cir. 1996) (dismissing RICO claim even though alleged overcharge was passed on to indirect purchaser). And the fact that a plaintiff may have incurred "increased costs in the form of the payment of benefits" is irrelevant. Several entities may have paid more as an ultimate consequence of the government's decision to establish AWP reimbursement, but that does not

mean that all these payors have standing under RICO against the drug companies. *See Laborers Local 17*, 191 F.3d at 239.[11]

Plaintiffs rely entirely on Judge Wolf's decision in *Sebago, Inc. v. Beazer East, Inc.*, 18 F. Supp.2d 70 (D. Mass. 1998), which is easily distinguishable. In *Sebago*, the plaintiffs were building or property owners who sued the manufacturer of the roofing insulation that caused damage to their roofs and properties. Unlike this case, the plaintiffs (or their predecessors) bought directly from defendants the products that allegedly damaged the plaintiffs' property. *Id.* at 78. There were no allegations of intervening causes, as in this case, and the plaintiffs were the direct purchasers, or at least the successors of those who were. For this reason, the court found that the plaintiffs were the directly injured parties. *Id.* at 84. The Court never held, as plaintiffs suggest, that merely alleging status as an "intended victim" was sufficient to show direct causation.[12]

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[11] The plaintiffs' citation to *In re Managed Care Litigation*, 185 F. Supp.2d 1310 (S.D. Fla. 2002), is misplaced. There, the plaintiffs were health plan participants unhappy with the rates charged by their own health plan. The Supreme Court in *Blue Shield of Virginia v. McCready*, 457 U.S. 465 (1982), had already ruled that the indirect purchaser bar did not prevent health plan subscribers from bringing antitrust claims against their health plans. Here, by contrast, the plaintiffs are at least one step removed from the plaintiffs in *Managed Care Litigation* -- they are not suing their health plan, or Medicare or the Medicare carriers, but the drug companies with whom they have no commercial relationship and to whom they made no payment.

[12] Moreover, the *Sebago* language selectively quoted by plaintiffs relates to an issue that we never raised -- whether a plaintiff must demonstrate detrimental reliance in order to state a civil RICO claim based on mail or wire fraud. In holding that detrimental reliance was not required, Judge Wolf in fact confirmed the Supreme Court's holding in *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258 (1992), that civil RICO "requires that the prohibited conduct constitute both the 'but for' cause (*i.e.*, 'cause-in-fact' or 'factual' cause) and proximate cause of the plaintiff's injury." 18 F. Supp.2d at 79 (citing *Holmes*, 503 U.S. at 268) (emphasis added).

C. The Court Should Reject Plaintiffs' Effort To Expand This Case To Cover Thousands Of Non-Medicare "Brand Name" Drugs.

Plaintiffs acknowledge that their Class 2 "PBM" allegations seek to turn this case into a massive dispute involving thousands of brand-name prescription drugs, not just the "450 or so" covered by Medicare. The supposed members of this putative class are the insurers of "more than 200 million Americans." Cplt. ¶¶ 170, 333. Plaintiffs also acknowledge that Rule 9(b) requires the Class 2 PBM allegations to set forth the "who, what, when, where and how" of the alleged fraud. Defendants' opening brief demonstrated that the Master Complaint contained none of these basics -- there were no particulars of how the alleged duping of Medicare extended to include non-Medicare drugs; none of the non-Medicare drugs was identified; and no PBM or "other intermediary" was ever identified. The opposition brief fails to justify these failures.

First, plaintiffs cite the parts of the Master Complaint relating to Medicare-covered drugs to support extending this case to non-Medicare drugs. Even if the allegations relating to the few Medicare-eligible drugs identified in the Master Complaint were sufficient to implicate those Medicare drugs, plaintiffs cannot multiply the number of drugs at issue in this case tenfold merely by saying "marketing the spread also happened with the non-Medicare drugs." As plaintiffs acknowledge, the non-Medicare eligible drugs in Class 2 are sold in an entirely different way (through PBMs) and paid for by an entirely different putative class of third-party payors not governed by Medicare's reimbursement rules. Indeed, the AWP statute does not even apply outside of the Medicare context; the private sector reimbursement is not fixed by law, but is freely negotiated among sophisticated parties in a competitive marketplace.

Second, plaintiffs still fail to identify a *single* "PBM or other intermediary" allegedly involved in the Class 2 claims. Nor do plaintiffs identify a single contractual relationship, let alone the required particulars about any such relationship, between a single third

party payor and a PBM, despite the fact that plaintiffs explicitly define Class 2 to include third party payors that "contracted with a PBM or other intermediary." Cplt. ¶ 333. Third, plaintiffs never address the fact that the Master Complaint provides no particulars about how *any* defendant "marketed the spread" to *any* PBM or other intermediary, or how any AWP for any non-Medicare "brand name drug" was inflated. Instead, all of the specific "examples" that plaintiffs cite in their brief, and all of the allegations in their Complaint, concern the AWPs for Medicare-eligible drugs.

It is preposterous for plaintiffs to propose launching a massive RICO action without identifying any of these elementary particulars. The Medicare-based claims asserted against more than 30 pharmaceutical defendants are already complex enough and, unless dismissed, will present formidable discovery and case management issues. Yet through their "Class 2" allegations, plaintiffs are trying to transform an already massive case into a totally unmanageable one involving thousands of drugs, made by multiple defendants, and sold through PBMs that operate entirely outside of Medicare. And they are trying to accomplish this unprecedented expansion without a single particular allegation concerning a single non-Medicare drug sold through a single PBM that contracted with a single third party payor. Rule 9(b) exists to prevent precisely such "fishing expeditions." *United States v. Parke-Davis,* 147 F. Supp.2d 39, 46 (D. Mass. 2001) (Saris, J.) (Rule 9(b) exists to prevent "conclusory allegations of fraud from serving as a basis for strike suits and fishing expeditions, and protecting defendants from groundless charges that may damage their reputations.").

IV. THE STATE LAW CLAIMS ARE PREEMPTED.

A. The Medicare Act and Regulations Preempt Plaintiffs' State Law Claims.

Contrary to plaintiffs' assertion that they are entitled to a presumption against preemption (Opp. at 41), any presumption against preemption gives way when "there has been a

history of significant federal presence [in a field]" of law. *United States v. Locke*, 529 U.S. 89, 108 (2000). Clearly, there has been and continues to be a "history of significant federal presence" in the field of Medicare drug reimbursement. *Congress of California Seniors v. Catholic Healthcare West*, 87 Cal. App. 4th 491, 496 (Cal. App. 2d Dist. 2001) ("there is no presumption . . . where, as with Medicare, there is a history of significant federal presence in the field").

Plaintiffs' reliance on the three "balance billing" cases is misplaced. These cases concerned how much additional money providers may collect from their Medicare beneficiaries, not how much the Medicare program pays providers. By contrast, by applying state laws to determine if plaintiffs' co-payments were excessive, this Court effectively would be deciding under states law how much the Medicare payment should have been. Indeed, plaintiffs' 20% co-payments derived entirely from how much Medicare paid providers; this Court cannot decide that co-payments were excessive without also ruling on how much Medicare should pay. This distinction from the "balance billing" cases is critical. While states may, under some circumstances, regulate how much a provider charges its patients, "traditionally states have played no role in setting Medicare rates and handling Medicare payments." *Medical Soc'y of the State of New York v. Cuomo*, 976 F.2d 812, 815 (2d Cir. 1992). How much Medicare pays is occupied by the federal government through the Medicare Act and regulations.

Catholic Healthcare West is the only case that involves the use of a state consumer statute to define what Medicare pays providers. There, the court concluded that "the Medicare statutes, regulations, manuals and administrative decisions lead ineluctably to the conclusion that federal law so comprehensively occupies the field of Medicare provider [] reimbursement that there remains no room for state involvement." 87 Cal. App. 4th at 509

(emphasis added). Thus, while *Catholic Healthcare West* involved, as plaintiffs observe, a different part of Medicare than that at issue here, that distinction is irrelevant because both cases concern Medicare provider reimbursement. Plaintiffs further try to distinguish *Catholic Healthcare West* on the basis that "plaintiffs' claims do not require proof of a violation of a federal statute or reexamination of agency rulemaking." *Id.* In fact, plaintiffs' claims require the Court to ignore federal statutes and agency rulemaking and redefine AWP.

Plaintiffs also fail to explain how their claims under 50 state laws can be reconciled with BIPA, in which Congress halted HHS' effort to equate AWP with market prices. To declare defendants' alleged conduct fraudulent under plaintiffs' theories and grant plaintiffs relief under state law, this Court would need to interpret AWP as approximating actual cost to providers or a "real average of real prices." Any such order would conflict with BIPA's prohibition on "directly or indirectly" decreasing the rate of reimbursement -- a prohibition that HHS has continued to observe in its most recent program directive, issued on December 3, 2002. *See* Attachment to Ex. 55, attached hereto.

Plaintiffs argue that HHS is now free to revise the AWP reimbursement system because the GAO issued its report. Yet even if HHS now has the authority to revise the way AWP is calculated -- a purported authority that it just recently declined to exercise, *see* Attachment to Ex. 55 -- that does not give private plaintiffs or the Court the right or authority to redefine AWP through state law claims. Doing so would "stand as an obstacle" to Congress' objectives in enacting BIPA of maintaining current drug reimbursement rates until *Congress* decides whether change is appropriate. Accordingly, the Court should dismiss plaintiffs' state law claims because BIPA preempts the state law claims.

B. ERISA Preempts The State Law Claims Of The Third Party Payor Plaintiffs And Many of The Individual Plaintiffs.

First, plaintiffs concede that the plaintiff employee benefit plans are ERISA plans that maintained benefit rules about whether and under what circumstances existing and new drugs are covered under the plan. Plaintiffs also make clear that the benefit plan plaintiffs paid the co-payments of their Medicare-eligible participants and beneficiaries. *See* Sobol Aff. at Ex. 3, ¶ 6; *Id.* at Ex. 4, ¶ 4. Plaintiffs also acknowledge that ERISA's preemption clause has been "liberally interpreted" to include state law claims that have a "connection with" or "reference to" an ERISA plan. Plaintiffs also do not contest that a state law claim is preempted when the "court's inquiry must be directed to the plan" to resolve the claim. *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 139-40 (1990). Indeed, the First Circuit has "consistently held that a cause of action 'relates to' an ERISA plan when a court must evaluate or interpret the terms of the ERISA-regulated plan to determine liability under the state law cause of action." *Hampers v. W.R. Grace & Co., Inc.*, 202 F.3d 44, 52 (1st Cir. 2000) (emphasis added).

Plaintiffs ignore the First Circuit cases, relying instead in a footnote (Pl. Opp. at 46 n.36) on *Stetson v. PFL Ins. Co.*, 16 F. Supp.2d 28 (D. Me. 1998). This case does not help plaintiffs at all. Although *Stetson* recognized that ERISA preemption is appropriate whenever "the court's inquiry must be directed to the plan," it concluded that the standard was not met in that particular case because the alleged misconduct had occurred before the plan was even in existence. *Id.* at 31-32. This is not the situation here. Equally irrelevant is *Carpenters Local Union No. 26 v. United States Fidelity & Guaranty Co.*, 215 F.3d 136, 139 (1st Cir. 2000), on which plaintiffs also rely. In *Carpenters Local,* the issue was whether a state bond statute, on its face, was preempted by ERISA, not, as in this case, whether the state law claims as applied to ERISA plans are preempted. *Carpenters Local* never even cited to, and certainly did not under-

mine, the First Circuit cases holding that preemption exists if the "court must evaluate or interpret the terms of the ERISA-regulated plan to determine liability under the state law cause of action." *Hampers*, 202 F.3d at 52.

In any event, plaintiffs never dispute that the Court will have to evaluate and interpret the terms of the ERISA plans to determine defendants' liability under the state law claims. Indeed, in responding to the motion to dismiss, the ERISA plans already have cited to the plan documents to describe the terms of the plans' drug benefits. *See* Affidavit of Julie Ryberg ¶¶ 5, 7; Aff. of Daniel Ryan ¶¶ 4, 6; Aff. of William Rhodes ¶¶ 4-5. Only by referring to these plans can the Court determine whether reimbursement for prescription drugs for a particular employer was based on AWP and the amount of the reimbursement that was required. *See Hampers*, 202 F.3d 44 at 52 ("We have held that ERISA preempts state law causes of action for damages where the damages must be calculated using the terms of an ERISA plan."); *Davis v. SmithKline Beecham Clinical Labs., Inc.* 993 F. Supp. 897, 899 (E.D. Pa. 1998) (ERISA preempted state consumer statutes because determining amount of overpayments would "require the examination and interpretation of ERISA plans setting forth the criteria for calculating such payments").

CONCLUSION

For the reasons stated in the opening and reply briefs, the Master Consolidated Class Action Complaint should be dismissed.

Respectfully submitted,

ON BEHALF OF THE FOLLOWING
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BOEHRINGER INGELHEIM CORP.; BEN VENUE LABORATORIES, INC.

DEY, INC.

FUJISAWA HEALTHCARE, INC.; FUJISAWA U.S.A., INC.

SMITHKLINE BEECHAM CORPORATION, D/B/A GLAXOSMITHKLINE

HOFFMANN -LA ROCHE INC.

IMMUNEX CORPORATION

JOHNSON & JOHNSON; CENTOCOR, INC.; ORTHO BIOTECH PRODUCTS, LLP

MERCK & CO., INC.

PFIZER, INC.

PHARMACIA CORPORATION; PHARMACIA & UPJOHN, INC.

SCHERING-PLOUGH CORPORATION; WARRICK PHARMACEUTICALS CORPORATION

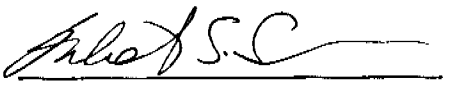
SICOR INC.; GENSIA, INC.; GENSIA SICOR PHARMACEUTICALS, INC.

WATSON PHARMA, INC.

Dated: December 20, 2002

CERTIFICATE OF SERVICE

I certify that on December 20, 2002, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service in accordance with Case Management Order No. 2.



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